



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-3327]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; E6(R2) Good Clinical Practice; International Council for Harmonisation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title “E6(R2) Good Clinical Practice; International Council for Harmonisation.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733; PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance on E6(R2) Good Clinical Practice; International Council for Harmonisation

OMB Control Number 0910-NEW

This information collection request supports Agency guidance entitled “E6(R2) Good Clinical Practice” (ICH E6(R2)), which was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. ICH E6(R2) amends the ICH guidance entitled “E6 Good Clinical Practice: Consolidated Guidance” (issued in April 1996) to encourage implementation of improved and more-efficient approaches to clinical trial design, conduct, oversight, recording, and reporting that are intended to increase clinical trial quality and efficiency while continuing to ensure human subject protection and reliability of trial results. Standards regarding electronic records and essential documents intended to increase clinical trial quality and efficiency have also been updated. The guidance includes additions to ICH E6(R1) that are identified as “ADDENDUM” and are marked with vertical lines on both sides of the text.

In table 1, we estimate that approximately 1,457 sponsors of clinical trials of human drugs will develop approximately 1,457 quality management systems per year (as described in ICH E6(R2) in section 5.0, including sections 5.0.1 to 5.0.7). We further estimate that it will take sponsors approximately 60 hours to develop and implement each quality management system, totaling 87,420 hours annually. The estimated number of sponsors who will develop a

quality management system, as described in ICH E6(R2), is based on the number of annual investigational new drug applications (INDs) and new drug applications (NDAs) submitted to the Center for Drug Evaluation and Research. The estimated number of hours it will take to develop a quality management system is based on FDA interactions with sponsors about activities that support drug development plans.

In table 2, we estimate that approximately 1,457 sponsors of clinical trials of human drugs will describe the quality management approach implemented in a clinical trial and summarize important deviations from the predefined quality tolerance limits and remedial actions taken in the clinical study report (as described in section 5.0.7 of ICH E6(R2)). We further estimate that sponsors will submit approximately 4.6 responses per respondent and that it will take sponsors 3 hours to complete this reporting task, totaling 20,107 reporting hours annually. These estimates are based on FDA's past experiences with INDs and NDAs.

In table 3, we estimate that approximately 218 sponsors of clinical trials of biological products will develop approximately 218 quality management systems per year (as described in ICH E6(R2) in section 5.0, including sections 5.0.1 to 5.0.7). We further estimate that it will take sponsors approximately 60 hours to develop and implement each quality management system, totaling 13,080 hours annually. The estimated number of sponsors who will develop a quality management system, as described in ICH E6(R2), is based on the number of annual INDs and biologics license application (BLAs) submitted to the Center for Biologics Evaluation and Research. The estimated number of hours it will take to develop a quality management system is based on FDA interactions with sponsors about activities that support drug development plans.

In table 4, we estimate that approximately 218 sponsors of clinical trials of biological products will describe the quality management approach implemented in a clinical trial and

summarize important deviations from the predefined quality tolerance limits and remedial actions taken in a clinical study report (as described in section 5.0.7 of ICH E6(R2)). We further estimate that sponsors will submit approximately 3.69 responses per respondent and that it will take sponsors 3 hours to complete this reporting task, totaling 2,413 reporting hours annually. As described previously, these estimates are based on past experiences with INDs and BLAs submitted to the Agency.

In the Federal Register of May 31, 2016 (81 FR 34345), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the proposed collection of information.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden for Human Drugs¹

E6(R2) Good Clinical Practice; International Council for Harmonisation; Guidance for Industry	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Section 5.0--Quality Management (including sections 5.0.1 to 5.0.7)	1,457	1	1,457	60	87,420
Developing a Quality Management System					

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Reporting Burden for Human Drugs¹

E6(R2) Good Clinical Practice; International Council for Harmonisation; Guidance for Industry	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Section 5.0.7--Risk Reporting	1,457	4.6	6,702	3	20,107
Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits and Remedial Actions Taken in the Clinical Study Report					

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3.--Estimated Annual Recordkeeping Burden for Biologics¹

E6(R2) Good Clinical Practice; International Council for Harmonisation; Guidance for Industry	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Section 5.0--Quality Management (including 5.0.1 to 5.0.7)	218	1	218	60	13,080
Developing a Quality Management System					

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 4.--Estimated Annual Reporting Burden for Biologics¹

E6(R2) Good Clinical Practice; International Council for Harmonisation; Guidance for Industry	No. of Responses	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Section 5.0.7--Risk Reporting	218	3.69	804	3	2,413
Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits and Remedial Actions Taken in the Clinical Study Report					

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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